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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,098

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EXAMINER

SHAW, AMANDA MARIE

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/553,098	<b>Applicant(s)</b> STROVEL ET AL.	
	<b>Examiner</b> Amanda Shaw	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 5-30,32-34,36,56-58,62,67-72,75,76 and 79-83 is/are pending in the application.
- 4a) Of the above claim(s) 9-30,32-34,36,56-58,62,67-72,75,76 and 79-83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-8 is/are rejected.
- 7) ☒ Claim(s) 5, 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/24/2009</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. Applicant's election without traverse of Group I (claims 5-8) in the reply filed on August 24, 2009 is acknowledged. Additionally Applicants election of SEQ ID NO: 107 (the HSPC150 gene) is acknowledged.

Claims 5-24, 28-30, 32-34, 36, 56-58, 62, 67-72, 75-76, and 79-83 are currently pending.

Claims 9-24, 28-30, 32-34, 36, 56-58, 62, 67-72, 75-76, and 79-83 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on August 24, 2009.

With respect to claims 5-8 the all of the genes (except for the elected gene, HSPC150) listed in Table 1 and all of the SEQ ID Nos (except for the elected sequence, SEQ ID NO: 107) listed in claim 8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on August 24, 2009.

### *Claim Objections*

2. Claims 5 and 8 are objected to for referring to specific figures and/or tables in the specification. MPEP 2173.05(s) states that "Where possible claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only

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in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into a claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience."

Claims 5 and 8 are objected to because claims still encompass genes and SEQ ID Nos which have not been elected. Prior to allowance of the claim, any non-elected subject matter that is not rejoined with any allowed elected subject matter will be required to be removed from the claim.

***Claim Rejections - 35 USC § 112 1<sup>st</sup> paragraph***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The following factors have been considered in formulating this rejection (*In re Wands*, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988): the breadth of the claims, the nature of the invention, the state of the prior art, the relative skill of those in the art, the

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predictability or unpredictability of the art, the amount of direction or guidance presented, the presence or absence of working examples of the invention and the quantity of experimentation necessary.

### **Nature of the Invention**

The invention is drawn to a method of diagnosing cancer or a precancerous condition in a mammal. The method comprises (a) obtaining a cell or tissue sample from a mammal suspected of having cancer or a precancerous condition and determining for said sample the gene copy number of the HSPC150 gene (b) comparing said gene copy number of step (a) to the gene copy number of the HSPC150 gene from a sample of a corresponding cell or tissue from a mammal of the same species not having cancer of the type being diagnosed whereby a higher gene copy number determined in step (a) relative to that in step (b) indicates the presence of a cancer or pre-cancerous condition in the mammal of step (a) and results in a diagnosis of cancer or a pre-cancerous condition in said mammal. Thus the nature of the invention requires a reliable association between an increased copy number of the HSPC150 gene and the presence of cancer or a precancerous condition. The invention is in a class of inventions which the CAFC has characterized as "the unpredictable arts such as chemistry and biology" (*Mycolgen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1330 (Federal Circuit 2001)).

### **Scope of the Claims:**

The claims encompass a method wherein the cancer or precancerous condition is any type of cancer (breast, colon, cervical, lung, brain etc) or any type of

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precancerous condition (actinic keratosis, atrophic gastritis, cervical dysplasia etc).

Only claim 7 is limited to specific cancers wherein the cancer is selected from the group consisting of breast, colon, lung, prostate, ovarian, pancreatic, cervical, and kidney cancer. Additionally the claims encompass a method for diagnosing cancer or a precancerous condition in any type of mammal (human, cat, whale, bat). Only claim 6 is limited to a specific type of mammal wherein the mammal is a human. Further the claims encompass obtaining a cell or tissue sample wherein the cell or tissue is derived from anywhere (i.e., saliva, hair, breast tissue).

#### **Teachings in the Specification and Examples:**

The specification teaches that the present invention relates to genes that have been identified as being amplified and/or over expressed, which can include increased copy number thereof, in cancerous cells. The genes have been identified through a combination of CGH, SKY, expression analysis, and reverse transcriptase PCR. The genes are listed in Table 1.

In the instant case the elected gene, HSPC150 protein similar to ubiquitin-conjugating enzyme, is listed in Table 1. Specifically Table provides the following information about HSPC150-- serial no: 119, SEQ ID NO: 107, Accession no: AI990409, tissue: breast, p\_m: metastatic, chromosome: 1, band: q32.1, unigene: Hs.5199.

The information present in Table 1 is problematic for several reasons. First of all Table 1 does not indicate if the HSPC150 gene is over expressed, if it has an increased copy number, or both. Here it is important to note that increased expression is not

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necessarily equivalent to increased copy number. The specification (page 27) even states that if a gene is found to be present in multiple copies it may not be actively being over expressed. Therefore based on the limited information provided in Table 1 the specification does not provide support for the HSPC150 gene having an increased copy number in cancer or pre cancerous conditions. Additionally it is noted that Table 1 teaches that the tissue is breast. Here its unknown if this means that the HSPC150 gene was only associated with breast cancer (opposed to the other types of cancers and pre cancerous conditions encompassed by the claims) or if this means that the HSPC150 gene was only detected in breast tissue samples (opposed to being detected in other types of samples encompassed by the claims). Further its unclear if the genes that were identified as being amplified and/or over expressed, were detected in a representative number of different types of mammals since the claims encompass any mammal.

**State of the Art and the Unpredictability of the Art:**

As discussed above the specification does not provide support for the HSPC150 gene having an increased copy number in cancer or precancerous conditions since Table 1 does not indicate if the HSPC150 gene was over expressed, if it had an increased copy number, or both. Stranger (Science 2007 Vol 315 pages 848-853) supports the argument that increased expression is not necessarily equivalent to increased copy number. Stranger teaches that evidence has been presented that increased copy number can be positively or negatively correlated with gene expression levels. For example deletion of a transcriptional repressor could serve to elevate gene

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expression (see page 849, col 1). For this reason a finding that the HSPC150 is over expressed in cancer or pre cancerous conditions would not necessarily mean that the HSPC150 has an increased copy number in cancer or precancerous conditions. If possible applicants should clarify if the HSPC150 gene actually had an increased copy number, if it was over expressed, or both.

Additionally even if the HSPC150 gene was found to have an increased copy number in breast cancer it is highly unpredictable as to whether the results obtained could be extrapolated to other cancers and pre cancerous conditions. For example Adnane (Oncogene 1991 Vol 6 pages 659-663) teaches that the analysis of 387 human breast tumor DNAs revealed that BEK (also called FGFR2) was amplified in about 12% of the cases (page 659, col 2). On the other hand Sasaki (Brain Tumor Pathology 2003 Vol 20 pages 59-63) teaches a genome microarray spotted with 287 target genes was used to analyze resected tissue from 11 different high grade gliomas. A high frequency of deleted genes was observed in 6 of 11 cases (54.5%), including FGFR2 (abstract). These papers are relevant to the present situation because they support the argument that it is highly unpredictable as to whether the amplification of HSPC150 in breast cancer could be extrapolated to other cancers and precancerous conditions.

Further even if the HSPC150 gene was found to have an increased copy number in humans with breast cancer it is highly unpredictable as to whether the results obtained could be extrapolated to other mammals. Knowledge that a particular gene such as HSPC150 is amplified in one organism (i.e. humans) with breast cancer does not allow one to conclude that this gene will also be amplified in other organisms with



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breast cancer.

**Quantity of Experimentation:**

In the instant case there is no evidence in the specification that increased copy number of HSPC150 is actually associated with cancer or precancerous conditions. For this reason one would have to conduct extensive experimentation. For example, such experimentation may involve using probes specific for HSPC150 gene to detect the copy number of the HSPC150 gene in large number of samples obtained from all different types of mammals with all different types of cancer and precancerous conditions. Such random, trial by error experimentation is considered to be undue. The specification has provided only an invitation to experiment.

**Conclusions:**

Taking into consideration the factors outlined above, including the nature of the invention and breadth of the claims, the state of the art, the level of skill in the art and its high level of unpredictability, the guidance provided by the applicant and the specific examples, it is the conclusion that an undue amount of experimentation would be required to make and use the invention.

***Conclusion***

4. No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571)

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272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached at 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw  
Examiner  
Art Unit 1634

/Stephen Kapushoc/  
Primary Examiner, Art Unit 1634